

# INTERNATIONAL SEARCH REPORT

Internal Application No  
PCT/GB 97/01087

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 C12N15/48 C07K14/15 A61K39/21 C07K16/10 C12Q1/70  
A01K67/027

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 C12N A61K C07K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
E	WO 97 21836 A (THE GENERAL HOSPITAL CORPORATION) 19 June 1997 see the whole document, especially SEQ ID NOs:2 and 3 and claims 1-38 ---	1-31
A	NATURE MEDICINE, vol. 1, no. 11, November 1995, page 1100 XP002037073 J.P. STOEY AND J.M. COFFIN: "The dangers of xenotransplantation" see the whole document ---	1-31
P,X	NATURE MEDICINE, vol. 3, no. 3, March 1997, pages 282-286, XP002037074 C. PATIENCE ET AL.: "Infection of human cells by an endogenous retrovirus of pigs" see the whole document -----	1-24,31

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

### \* Special categories of cited documents :

- \* "A" document defining the general state of the art which is not considered to be of particular relevance
- \* "E" earlier document but published on or after the international filing date
- \* "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \* "O" document referring to an oral disclosure, use, exhibition or other means
- \* "P" document published prior to the international filing date but later than the priority date claimed

- \* "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \* "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \* "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- \* "&" document member of the same patent family

Date of the actual completion of the international search

7 August 1997

Date of mailing of the international search report

14. 08. 97

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+ 31-70) 340-3016

Authorized officer

Cupido, M

*FOR THE PURPOSES OF INFORMATION ONLY*

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

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PCT

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

International Application No.

International Filing Date

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference  
(if desired) (12 characters maximum)

MGH/PL

Box No. I	TITLE OF INVENTION	
	"Porcine Retrovirus"	
Box No. II	APPLICANT	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (i.e. country) of residence if no State of residence is indicated below.)		<input type="checkbox"/> This person is also inventor.
Q-One Biotech Ltd. Todd Campus West of Scotland Science Park Glasgow G20 OXA  UNITED KINGDOM		Telephone No.  Facsimile No.  Teleprinter No.
State (i.e. country) of nationality: GB		State (i.e. country) of residence: GB
This person is applicant for the purposes of: <input type="checkbox"/> all designated States <input checked="" type="checkbox"/> all designated States except the United States of America <input type="checkbox"/> the United States of America only <input type="checkbox"/> the States indicated in the Supplemental Box		
Box No. III	FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (i.e. country) of residence if no State of residence is indicated below.)		This person is: <input checked="" type="checkbox"/> applicant only <input type="checkbox"/> applicant and inventor <input type="checkbox"/> inventor only (If this check-box is marked, do not fill in below.)
Imutran Ltd. Douglas House 18 Trumpington Road. Cambridge CB2 2AH  UNITED KINGDOM		
State (i.e. country) of nationality: GB		State (i.e. country) of residence: GB
This person is applicant for the purposes of: <input type="checkbox"/> all designated States <input checked="" type="checkbox"/> all designated States except the United States of America <input type="checkbox"/> the United States of America only <input type="checkbox"/> the States indicated in the Supplemental Box		
<input checked="" type="checkbox"/> Further applicants and/or (further) inventors are indicated on a continuation sheet.		
Box No. IV	AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE	
The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as:		<input type="checkbox"/> agent <input type="checkbox"/> common representative
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)		Telephone No.
McCALLUM, William Potter; MacDOUGALL, Donald Carmichael; SZCZUKA, Jan Tymoteusz; NAISMITH, Robert Stewart; HORNER, Martin Grenville; STOKES, Graeme Wilson; JONES, Andrée Zena; SHANKS, Andrew; NEWELL, Campbell; KERR, Sheila Agnes Fife; GODWTN, Edgar James; all of		0141 221 5767
CRUIKSHANK & FAIRWEATHER, 19 ROYAL EXCHANGE SQUARE, GLASGOW G1 3AE, UNITED KINGDOM		Facsimile No. 0141 221 7739
		Teleprinter No.
<input type="checkbox"/> Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.		

## Continuation of Box No. III FURTHER APPLICANTS AND/OR (FURTHER) INVENTORS

If none of the following sub-boxes is used, this sheet is not to be included in the request.

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (i.e. country) of residence if no State of residence is indicated below.)

GALBRAITH Daniel, Norman  
-----  
26 Don Street  
Glasgow  
G33 2DH UNITED KINGDOM

This person is:

☐ applicant only☒ applicant and inventor☐ inventor only (If this check-box is marked, do not fill in below.)

State (i.e. country) of nationality:

GB

State (i.e. country) of residence:

GB

This person is applicant for the purposes of:

☐ all designated States☐ all designated States except the United States of America☒ the United States of America only☐ the States indicated in the Supplemental Box

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (i.e. country) of residence if no State of residence is indicated below.)

HAWORTH Christine  
-----  
139 Marlborough Avenue.  
Broomhill  
Glasgow  
G11 7JE UNITED KINGDOM

This person is:

☐ applicant only☒ applicant and inventor☐ inventor only (If this check-box is marked, do not fill in below.)

State (i.e. country) of nationality:

GB

State (i.e. country) of residence:

GB

This person is applicant for the purposes of:

☐ all designated States☐ all designated States except the United States of America☒ the United States of America only☐ the States indicated in the Supplemental Box

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (i.e. country) of residence if no State of residence is indicated below.)

LEES Gillian, Margaret  
-----  
5 Kirkvale Drive.  
Newton Mearns  
Glasgow  
G77 5HD UNITED KINGDOM

This person is:

☐ applicant only☒ applicant and inventor☐ inventor only (If this check-box is marked, do not fill in below.)

State (i.e. country) of nationality:

GB

State (i.e. country) of residence:

GB

This person is applicant for the purposes of:

☐ all designated States☐ all designated States except the United States of America☒ the United States of America only☐ the States indicated in the Supplemental Box

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (i.e. country) of residence if no State of residence is indicated below.)

SMITH Kenneth, Thomas  
-----  
5 Kirkvale Drive  
Newton Mearns  
Glasgow  
G77 5HD UNITED KINGDOM

This person is:

☐ applicant only☒ applicant and inventor☐ inventor only (If this check-box is marked, do not fill in below.)

State (i.e. country) of nationality:

GB

State (i.e. country) of residence:

GB

This person is applicant for the purposes of:

☐ all designated States☐ all designated States except the United States of America☒ the United States of America only☐ the States indicated in the Supplemental Box

☐ Further applicants and/or (further) inventors are indicated on another continuation sheet.

See Notes to the request form

## Box No.V DESIGNATION OF STATES

The following designations are hereby made under Rule 4.9(a) (mark the applicable check-boxes; at least one must be marked):

## Regional Patent

- ☒ AP **ARIPO Patent:** KE Kenya, LS Lesotho, MW Malawi, SD Sudan, SZ Swaziland, UG Uganda, and any other State which is a Contracting State of the Harare Protocol and of the PCT
- ☒ EA **Eurasian Patent:** AM Armenia, AZ Azerbaijan, BY Belarus, KG Kyrgyzstan, KZ Kazakhstan, MD Republic of Moldova, RU Russian Federation, TJ Tajikistan, TM Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT
- ☒ EP **European Patent:** AT Austria, BE Belgium, CH and LI Switzerland and Liechtenstein, DE Germany, DK Denmark, ES Spain, FI Finland, FR France, GB United Kingdom, GR Greece, IE Ireland, IT Italy, LU Luxembourg, MC Monaco, NL Netherlands, PT Portugal, SE Sweden, and any other State which is a Contracting State of the European Patent Convention and of the PCT
- ☒ OA **OAPI Patent:** BF Burkina Faso, BJ Benin, CF Central African Republic, CG Congo, CI Côte d'Ivoire, CM Cameroon, GA Gabon, GN Guinea, ML Mali, MR Mauritania, NE Niger, SN Senegal, TD Chad, TG Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT (if other kind of protection or treatment desired, specify on dotted line)

## National Patent (if other kind of protection or treatment desired, specify on dotted line):

- |  |  |
|--|--|
| <input checked="" type="checkbox"/> AL Albania                               | <input checked="" type="checkbox"/> LU Luxembourg                                |
| <input checked="" type="checkbox"/> AM Armenia                               | <input checked="" type="checkbox"/> LV Latvia                                    |
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| <input checked="" type="checkbox"/> BA Bosnia and Herzegovina                | <input checked="" type="checkbox"/> MN Mongolia                                  |
| <input checked="" type="checkbox"/> BB Barbados                              | <input checked="" type="checkbox"/> MW Malawi                                    |
| <input checked="" type="checkbox"/> BG Bulgaria                              | <input checked="" type="checkbox"/> MX Mexico                                    |
| <input checked="" type="checkbox"/> BR Brazil                                | <input checked="" type="checkbox"/> NO Norway                                    |
| <input checked="" type="checkbox"/> BY Belarus                               | <input checked="" type="checkbox"/> NZ New Zealand                               |
| <input checked="" type="checkbox"/> CA Canada                                | <input checked="" type="checkbox"/> PL Poland                                    |
| <input checked="" type="checkbox"/> CH and LI Switzerland and Liechtenstein  | <input checked="" type="checkbox"/> PT Portugal                                  |
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| <input checked="" type="checkbox"/> CU Cuba                                  | <input checked="" type="checkbox"/> RU Russian Federation                        |
| <input checked="" type="checkbox"/> CZ Czech Republic                        | <input checked="" type="checkbox"/> SD Sudan                                     |
| <input checked="" type="checkbox"/> DE Germany                               | <input checked="" type="checkbox"/> SE Sweden                                    |
| <input checked="" type="checkbox"/> DK Denmark                               | <input checked="" type="checkbox"/> SG Singapore                                 |
| <input checked="" type="checkbox"/> EE Estonia                               | <input checked="" type="checkbox"/> SI Slovenia                                  |
| <input checked="" type="checkbox"/> ES Spain                                 | <input checked="" type="checkbox"/> SK Slovakia                                  |
| <input checked="" type="checkbox"/> FI Finland                               | <input checked="" type="checkbox"/> TJ Tajikistan                                |
| <input checked="" type="checkbox"/> GB United Kingdom                        | <input checked="" type="checkbox"/> TM Turkmenistan                              |
| <input checked="" type="checkbox"/> GE Georgia                               | <input checked="" type="checkbox"/> TR Turkey                                    |
| <input checked="" type="checkbox"/> HU Hungary                               | <input checked="" type="checkbox"/> TT Trinidad and Tobago                       |
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| <input checked="" type="checkbox"/> IS Iceland                               | <input checked="" type="checkbox"/> UG Uganda                                    |
| <input checked="" type="checkbox"/> JP Japan                                 | <input checked="" type="checkbox"/> US United States of America                  |
| <input checked="" type="checkbox"/> KE Kenya                                 | <input checked="" type="checkbox"/> UZ Uzbekistan                                |
| <input checked="" type="checkbox"/> KG Kyrgyzstan                            | <input checked="" type="checkbox"/> VN Viet Nam                                  |
| <input checked="" type="checkbox"/> KP Democratic People's Republic of Korea |  |
| <input checked="" type="checkbox"/> KR Republic of Korea                     |  |
| <input checked="" type="checkbox"/> KZ Kazakhstan                            |  |
| <input checked="" type="checkbox"/> LC Saint Lucia                           |  |
| <input checked="" type="checkbox"/> LK Sri Lanka                             |  |
| <input checked="" type="checkbox"/> LR Liberia                               |  |
| <input checked="" type="checkbox"/> LS Lesotho                               |  |
| <input checked="" type="checkbox"/> LT Lithuania                             |  |

Check-boxes reserved for designating States (for the purposes of a national patent) which have become party to the PCT after issuance of this sheet:

- ☒ YU Yugoslavia
- ☒ GH Ghana
- ☒
- ☒

In addition to the designations made above, the applicant also makes under Rule 4.9(b) all designations which would be permitted under the PCT except the designation(s) of \_\_\_\_\_

The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. (Confirmation of a designation consists of the filing of a notice specifying that designation and the payment of the designation and confirmation fees. Confirmation must reach the receiving Office within the 15-month time limit.)

**Box No. VI PRIORITY CLAIM**Further priority claims are indicated in the Supplemental Box ☐

The priority of the following earlier application(s) is hereby claimed:

Country (in which, or for which, the application was filed)	Filing Date (day/month/year)	Application No.	Office of filing (only for regional or international application)
item (1)  GB	19 April 1996.	GB 9608164.1	
item (2)  GB	10 February 1997.	GB 9702668.6	
item (3)			

Mark the following check-box if the certified copy of the earlier application is to be issued by the Office which for the purposes of the present international application is the receiving Office (a fee may be required):

☒ The receiving Office is hereby requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) identified above as item(s): 1 & 2
**Box No. VII INTERNATIONAL SEARCHING AUTHORITY**

Choice of International Searching Authority (ISA) (If two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used):

ISA /

Earlier search Fill in where a search (international, international-type or other) by the International Searching Authority has already been carried out or requested and the Authority is now requested to base the international search, to the extent possible, on the results of that earlier search. Identify such search or request either by reference to the relevant application (or the translation thereof) or by reference to the search request.

Country (or regional Office):

Date (day/month/year):

Number:

**Box No. VIII CHECK LIST**

This international application contains the following number of sheets:

1. request : 4 sheets  
 2. description : 37 sheets  
 3. claims : 6 sheets  
 4. abstract : 1 sheets  
 5. drawings : 22 sheets

Total : 70 sheets

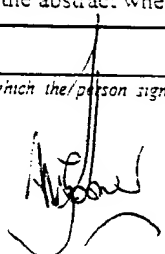
This international application is accompanied by the item(s) marked below:

1. ☐ separate signed power of attorney  
 2. ☐ copy of general power of attorney  
 3. ☐ statement explaining lack of signature  
 4. ☐ priority document(s) identified in Box No. VI as item(s):  
 5. ☒ fee calculation sheet  
 6. ☐ separate indications concerning deposited microorganisms  
 7. ☐ nucleotide and/or amino acid sequence listing (diskette)  
 8. ☐ other (specify):

Figure No. \_\_\_\_\_ of the drawings (if any) should accompany the abstract when it is published.

**Box No. IX SIGNATURE OF APPLICANT OR AGENT**

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).



Dr. M.G. Horner.

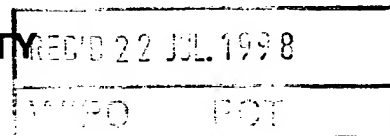
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1. Date of actual receipt of the purported international application:	2. Drawings:  <input type="checkbox"/> received:  <input type="checkbox"/> not received:
3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:	
4. Date of timely receipt of the required corrections under PCT Article 11(2):	
5. International Searching Authority specified by the applicant: ISA /	6. <input type="checkbox"/> Transmittal of search copy delayed until search fee is paid

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# PATENT COOPERATION TREATY



## PCT

### INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference MGH/PC/SC/P07662PC	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (PCT/IPEA/416)	
International application No. PCT/GB97/01087	International filing date (day/month/year) 18/04/1997	Priority date (day/month/year) 19/04/1996
International Patent Classification (IPC) or national classification and IPC C12N15/48		
Applicant Q-ONE BIOTECH LTD. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 5 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand  14/11/1997	Date of completion of this report
Name and mailing address of the IPEA/   European Patent Office D-80298 Munich Tel. (+49-89) 2399-0, Tx: 523656 epmu d Fax: (+49-89) 2399-4465	Authorized officer  Sprinks, M  Telephone No. (+49-89) 2399-8706 

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/GB97/01087

**I. Basis of the report**

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

**Description, pages:**

1-37 as originally filed

**Claims, No.:**

1-30 as received on 24/06/1998 with letter of 24/06/1998

**Drawings, sheets:**

1/6-6/6 as originally filed

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:  
☒ the claims, Nos.: 31  
☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application.  
☒ claims Nos. 30.

because:



# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB97/01087

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):
- ☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 30 are so unclear that no meaningful opinion could be formed (*specify*):

**see separate sheet**

- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☐ no international search report has been established for the said claims Nos. .

## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. Statement

Novelty (N)	Yes: Claims 1-29
	No: Claims
Inventive step (IS)	Yes: Claims 1-14, 16-29
	No: Claims 15
Industrial applicability (IA)	Yes: Claims 1-29
	No: Claims

### 2. Citations and explanations

**see separate sheet**

## VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

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International application No. PCT/GB97/01087

The following documents (D) are mentioned for the first time in this report; the numbering will be adhered to in the rest of the procedure:

D1...Nature Medicine, vol.1, no.11, 1995, page 1100 (Stoye et al.)

**III) Non-establishment of opinion**

**Clarity**

- 1) Exactly what should be examined in **claim 30** is impossible to determine because the formulation is so broad. Consequently, no meaningful assessment of novelty, inventive step and industrial applicability could be made.

**V) Reasoned statement**

**Novelty, inventive step and industrial applicability**

- 1) The present application does not satisfy the criterion set forth in **Article 33 (3) PCT** because the subject-matter of **claim 15** does not involve an inventive step (**Rule 65.1 and 65.2 PCT**). Said claim broadly refers to a vaccine comprising an inactivated PoEV virus which would be obvious to one of skill in the art in the light of D1 and common practice.
- 2) **Claims 1-14 and 16-29** are considered to fulfil the criteria of **Article 33 (2) - (4) PCT** since, in the light of the available prior art, they define what appears to be new, inventive and industrially applicable subject-matter, namely specific porcine retroviral sequences which do not appear to have been disclosed or suggested in the available prior art.
- 3) For the assessment of the present **claim 29** on the question whether it is industrially applicable, no unified criteria exist in the PCT. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but will allow, however, claims to a known compound for first use in medical treatment and the use of such a

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

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International application No. PCT/GB97/01087

compound for the manufacture of a medicament for a new medical treatment.

The applicant is also requested to note that the wording "for use in therapy" (and equivalents thereof) has no limiting effect under the **PCT**.

**VIII) Certain observations**

**Clarity**

- 1) The present application does not satisfy the criterion set forth in **Article 6 PCT** because the subject-matter of **claims 12-14 and 16** is unclear.
- 2) **Claims 12 and 13** refer to polypeptides with % sequence identities to proteins with particular functions. However, because no such functions have been defined for the polypeptides claimed, they need not provide any technical effect according to the invention. Similar is true of the "derivative" polypeptide of **claim 14**, since the physiological and/or immunological activities referred to therein are not clearly defined.
- 3) The antibody of **claim 16** is still not defined as being specific for its target molecule. Consequently, the subject-matter of said claim is unclear because it covers non-specific, cross-reacting antibodies which would not provide a technical effect appropriate to the present invention.

claims

1. An isolated polynucleotide fragment:
  - (a) encoding at least one porcine retrovirus (PoEV) expression product;
  - (b) encoding a physiologically active and/or immunogenic derivative of said expression product; or
  - (c) which is complementary to a polynucleotide sequence as defined in (a) or (b).
2. An isolated polynucleotide fragment according to claim 1:
  - (a) encoding the polymerase (POL) polypeptide;
  - (b) encoding a physiologically active and/or immunogenic derivative of a polypeptide as described in (a); or
  - (c) which is complementary to a polynucleotide sequence as defined in (a) or (b).
3. An isolated polynucleotide fragment according to claim 1:
  - (a) encoding the virion core polypeptide (GAG) and/or envelope polypeptide (ENV);
  - (b) encoding a physiologically active and/or immunogenic derivative of a polypeptide as described in (a); or
  - (c) which is complementary to a polynucleotide sequence as defined in (a) or (b).

Replaced by Article 34

4. An isolated polynucleotide fragment according to claim 1:
  - (a) encoding the virion core polypeptide (GAG), polymerase (POL) and envelope polypeptide (ENV);
  - (b) encoding a physiologically active and/or immunogenic derivative of a polypeptide as described in (a); or
  - (c) which is complementary to a polynucleotide sequence as defined in (a) or (b).
5. An isolated polynucleotide fragment according to any one of claims 1 to 4 wherein the polynucleotide fragments is a deoxyribose nucleic acid (DNA) fragment.
6. An isolated polynucleotide fragment according to any preceding claim encoding:
  - (a) said at least one polypeptide having an amino acid sequence which is shown in Figures 3 or 4;
  - (b) encoding a polypeptide which is a physiologically active and/or immunogenic derivative of at least one of the polypeptides defined in (a); or
  - (c) which is complementary to a polynucleotide sequence as defined in (a) or (b).
7. An isolated polynucleotide fragment according to any preceding claim;
  - (a) comprising at least one of the ORFs shown in Figures 1, 2, 3 or 4 or comprising a corresponding RNA sequence;

- (b) comprising a sequence having substantial nucleotide sequence identity with a sequence as described in (a) above; or
  - (c) comprising a sequence which is complementary to a sequence as described in (a) or (b) above.
- 
- 8. A recombinant nucleic acid molecule comprising a polynucleotide fragment according to any one of claims 1 to 7.
  - 9. A recombinant nucleic acid molecule according to claim 8 wherein the recombinant nucleic acid molecule comprises regulatory control sequences operably linked to said polynucleotide fragment for controlling expression of said polynucleotide fragment.
  - 10. A vector comprising a recombinant nucleic acid molecule according to either of claims 8 or 9.
  - 11. A vector according to claim 10 which is a virus or a plasmid.
  - 12. A prokaryotic or eukaryotic host cell transformed by a polynucleotide fragment, recombinant nucleic acid molecule, or vector according to any of claims 1 to 11.

13. A recombinant PoEV polypeptide or derivative thereof displaying POL PoEV physiological and/or immunogenic activity.
14. A recombinant PoEV polypeptide or derivative thereof displaying GAG and/or ENV PoEV physiological and/or immunogenic activity.
15. A recombinant PoEV polypeptide or derivative thereof displaying GAG, POL and ENV PoEV physiological and/or immunogenic activity.
16. A recombinant PoEV polypeptide according to any one of claims 13 to 15 comprising a sequence as shown in Figures 3 or 4, or functionally active derivative thereof.
17. A vaccine comprising a recombinant PoEV polypeptide according to any one of claims 13 to 16, or an inactivated PoEV virus and a pharmaceutically acceptable carrier.
18. An antibody or fragment thereof capable of binding to a polypeptide or fragment according to any one of claims 13 or 16.
19. A polynucleotide primer which is PoEV specific.
20. A polynucleotide probe which is capable of specifically hybridising to a PoEV polynucleotide sequence.

21. A probe or a primer according to claims 19 or 20 which has substantial nucleotide sequence identity with a strand of the molecule depicted in Figures 1, 2, 3 or 4 or a strand complementary therewith, with a corresponding RNA molecule, or with a part of such a molecule.
22. A PoEV detection kit comprising a polynucleotide primer or probe according to any of claims 19 to 21.
23. Use of a PoEV specific polynucleotide in the detection of PoEV in a sample.
24. Use of a PoEV specific polynucleotide in a PCR for the detection of PoEV in a sample.
25. A pig modified so as to not express an infectious PoEV capable of infecting humans.
26. Cells, tissues or organs obtainable from a pig according to claim 25.
27. Use of a recombinant PoEV polypeptide according to any one of claims 13 to 16 in the preparation of a vaccine.
28. Use of a polynucleotide primer or probe according to any of claims 19 to 21 in the preparation of a detection kit capable of detecting the presence of PoEV nucleic acid in a sample.



29. Use of a polynucleotide; polypeptide; cells, tissues or organs according to any one of claims 1 to 7, 13 to 16 or 26 in therapy or diagnosis.
30. A polynucleotide; polypeptide; cells, tissues or organs according to any one of claims 1 to 7, 13 to 16 or 26 in the preparation of a medicament for use in therapy or diagnosis.
31. The invention substantially as hereinbefore described.

# PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference <b>MGH/PC</b>	<b>FOR FURTHER ACTION</b> see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. <b>PCT/GB 97/ 01087</b>	International filing date (day/month/year) <b>18/04/1997</b>	(Earliest) Priority Date (day/month/year) <b>19/04/1996</b>
Applicant  <b>Q-ONE BIOTECH LTD. et al.</b>		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. ☒ Certain claims were found unsearchable (see Box I).

2. ☐ Unity of invention is lacking (see Box II).

3. ☒ The international application contains disclosure of a nucleotide and/or amino acid sequence listing and the international search was carried out on the basis of the sequence listing

☐ filed with the international application.

☒ furnished by the applicant separately from the international application,

☐ but not accompanied by a statement to the effect that it did not include matter going beyond the disclosure in the international application as filed.

☐ Transcribed by this Authority

4. With regard to the title, ☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this International Search Report, submit comments to this Authority.

6. The figure of the drawings to be published with the abstract is:

Figure No. none ☐ as suggested by the applicant.

☐ None of the figures.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/GB 97/01087

**Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 29  
because they relate to subject matter not required to be searched by this Authority, namely:  
Although this claim, insofar in vivo uses are concerned, is directed to a method of treatment and a diagnostic method practised on the human/animal body the search has been carried out based on the alleged effects of the compounds.
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 97/01087

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 C12N15/48 C07K14/15 A61K39/21 C07K16/10 C12Q1/70  
A01K67/027

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 C12N A61K C07K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
E	WO 97 21836 A (THE GENERAL HOSPITAL CORPORATION) 19 June 1997 see the whole document, especially SEQ ID NOs:2 and 3 and claims 1-38 ---	1-31
A	NATURE MEDICINE, vol. 1, no. 11, November 1995, page 1100 XP002037073 J.P. STOEY AND J.M. COFFIN: "The dangers of xenotransplantation" see the whole document ---	1-31
P,X	NATURE MEDICINE, vol. 3, no. 3, March 1997, pages 282-286, XP002037074 C. PATIENCE ET AL.: "Infection of human cells by an endogenous retrovirus of pigs" see the whole document -----	1-24,31



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

## \* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance  
"E" earlier document but published on or after the international filing date  
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)  
"O" document referring to an oral disclosure, use, exhibition or other means  
"P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention  
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone  
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art  
"&" document member of the same patent family

Date of the actual completion of the international search

7 August 1997

Date of mailing of the international search report

14. 08. 97

Name and mailing address of the ISA

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Authorized officer

Cupido, M

# INTERNATIONAL SEARCH REPORT

## Information on patent family members

### Information on patent family members

**International Application No**

PCT/GB 97/01087

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9721836 A	19-06-97	NONE	
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## PATENT COOPERATION TREATY

PCT

## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

United States Patent and Trademark  
Office  
(Box PCT)  
Crystal Plaza 2  
Washington, DC 20231  
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

<b>Date of mailing (day/month/year)</b> 28 November 1997 (28.11.97)	
<b>International application No.</b> PCT/GB97/01087	<b>Applicant's or agent's file reference</b> MGH/PC
<b>International filing date (day/month/year)</b> 18 April 1997 (18.04.97)	<b>Priority date (day/month/year)</b> 19 April 1996 (19.04.96)
<b>Applicant</b> GALBRAITH, Daniel, Norman et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:

14 November 1997 (14.11.97)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was  
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

<p>The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland</p> <p>Facsimile No.: (41-22) 740.14.35</p>	<p>Authorized officer Catherine Massetti</p> <p>Telephone No.: (41-22) 338.83.38</p>
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